IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	S. Bailey, et al.	Attorney Docket:	6006-009
Serial No.:	09/783,633	Examiner:	T. Barrett
Filed:	February 14, 2001	Art Unit:	3738
Title:	IN VIVO SENSOR AND METHOD OF MAKING SAME	Customer No.:	29,335

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I hereby certify that this document (along with any being referred to as enclosed and/or attached) are being filed electronically on this the 5th day of January, 2007, addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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APPELLANT'S AMENDED BRIEF ON APPEAL

This amended Appeal Brief is being filed in response to the Notification of Non-Compliant Appeal Brief mail dated December 5, 2006.

1. Real Party In Interest

The real party in interest for this patent application is Advanced Bio Prosthetic Surfaces, L.L.C., the assignee of the application.

2. Related Appeals and Interferences

No related appeals or interferences exist with reference to the above referenced patent application.

3. Status of Claims

Claims 1-47, 50, and 67 have been cancelled. Claims 48-49 and 51-66 stand rejected under 35 U.S.C. §102(b) as being anticipated by EP 0 759 730 B1 to Burmeister et al. (hereinafter referred to as "*Burmeister*"). The rejection of claims 48-49 and 51-66 is under appeal.

4. Statement of Amendments

An amendment to claim 48 was filed after final rejection and was denied entry. The after-final amendment of claim 48 was denied entry because it purportedly represented new issues that would require further consideration and search.

5. Summary of Claimed Subject Matter

Claim 48 is the sole independent claim pending in the application. Antecedent support for each element in claim 48 is noted in the parentheses following each claim element:

Claim 48. An implantable sensor device having a plurality of structural elements (page 21, line 23 – page 22, line 6; Figure 7B) capable of expanding within an anatomical passageway (page 2, lines 3-9; page 6, line 14 – page 7, line 10; page 21, line 29 – page 22, line 6; Figure 7A and Figure 7B) comprising first and second structural elements (page 21, line 23 – page 22, line 6; Figure 7B) where at least some of the plurality of first structural elements further comprise at least one first sensor element (page 23, lines 22 – 26) and where at least some of the plurality of second structural elements further comprise at least one second sensor element (page 23, lines 22-26), both sensors which selectively detect an energy stimulus and responds to the detection of the energy stimulus (page 16, lines 11-15) by altering the geometry or conformational profile of the device body member (page 22, lines 10-18).

6. Grounds of Rejection to be Reviewed on Appeal

Whether claims 48-49 and 51-66 are unpatentable under 35 U.S.C. § 102(b) over *Burmeister*.

7. Argument

Rejection of claims 48-49 and 51-66 under 35 U.S.C. § 102(b) over *Burmeister*

The Examiner has finally rejected claims 48-49 and 51-66 under 35 U.S.C. §102(b) as being anticipated by *Burmeister*. The Examiner has taken the position that *Burmeister* purportedly discloses:

> an implantable sensor device made of a superelastic material which can be laminated (col. 6, lines 27-36) having a plurality of structural elements capable of expanding within an anatomical passageway comprising a sensor element that selectively detects an energy stimulus, i.e. body temperature, and responds to the detection of the energy stimulus by altering the geometry of the device body member, i.e. expansion. This expansion is inherently detectable with non-invasive radiographs, especially when using radiopaque portions of coatings (col. 11, lines 35-37).

Final Office Action of May 18, 2006, at page 3. The Examiner further noted that the claimed "energy source" recited in claim 48 "is not positively claimed, so because the above-cited [*Burmeister*] devices are **capable** of 'detecting' the source, they meet the limitations." *Id.*

In order for *Burmeister* to anticipate claims 48-49 and 51-66, this single reference must disclose each and every element of claims 48-49 and 51-66, either expressly or inherently, and *Burmeister* must also enable one skilled in the art to make and use the invention in a manner that anticipates the claimed invention. *See Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1574 (Fed. Cir. 1986) (holding that if a prior art reference fails to disclose even one element of the claimed invention, then that claimed invention is not anticipated). For reasons as subsequently recited herein, Applicant submits that *Burmeister* fails to disclose each and every element of claims 48-49 and 51-66, let alone enable one skilled in the art to make and use the invention in a manner that anticipates the claimed invention. Accordingly, Applicant submits

that the Examiner's anticipation rejection is improper and respectfully requests reconsideration of the present application.

A. *Burmeister* fails to teach a sensor element that is a distinct element from the structural elements, as recited in claim 48.

For the Examiner's 35 U.S.C. §102(b) anticipation rejection to be proper, *Burmeister* must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and its existence was recognized by those of ordinary skill in the field of the invention. *See* MPEP §2131; s*ee also In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (stating that "the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it"); *see also Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 304 F.3d 1221, 1230 (Fed. Cir. 2002) (holding that " 'anticipation' in the patent sense means that the subject matter was previously known. A precatory suggestion of general procedures that may or may not succeed in producing the novel product, a product that has not previously been produced, does not convert the suggested product into a previously existing product"); *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (holding that "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." [Emphasis added]); *see also Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (stating that anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"). Additionally, while an identity of terminology is not required, the elements must nonetheless be arranged as required by the claim. *See In re Bond*, 910 F.2d 831, 832-833 (Fed. Cir. 1990) (holding that anticipation can not be established by mere equivalents).

Claim 48 recites an implantable sensor device having a plurality of structural elements comprising first and second structural elements where at least some of the plurality of first structural elements further comprise at least one first sensor element and where at least some of the plurality of second structural elements further comprise at least one second sensor element. As construed by an ordinary reader skilled in the art, the term "further comprise", as applied in the framework of currently written claim 48, clearly indicates that the recited sensor elements are entities that are distinct from the recited structural elements. In other words, the structural

elements and the sensor elements of the claimed invention are recited as individual elements. Thus, in the claimed invention, the sensor elements do not form the entire stent structure itself.

In the Final Office Action of May 18, 2006, the Examiner seems to acknowledge that the phrase "further comprise" denotes at least two distinct elements. *See* page 2, paragraph 3, where the Examiner references *Burmeister* and recognizes the structural elements and the sensor elements as being distinct when he argued that:

> [t]he structural element of strands 12 could be considered the martensitic layer, which is capable of expanding, e.g. by balloon as disclosed in Burmeister, and the self-expanding austenitic layer of strand 12 could be considered the sensor element. Strands 14 would have similar layers. [Emphasis added]

While Applicant agrees with the Examiner's interpretation of claim 48 to define the sensor element as being an element distinct from the structural element, Applicant respectfully submits that the Examiner's overall argument in the above-recited passage is substantially incorrect. Contrary to the Examiner's assertion in the above-recited passage, *Burmeister* never discloses that portions of its stent's strands 12 are to be in a martensitic state, while at the same time, other portions of the said strands 12 are to be in an austenitic state. *Burmeister* merely teaches a stent 10 that is constructed entirely of two components, *i.e.*, strands 12 and strands 14. *See Burmeister*, paragraph 18. In fact, *Burmeister* never even specifies which phase (*i.e.*, martensitic or austenitic) the two components, strands 12 and strands 14, are in.

In view of *Burmeister's* disclosure of a stent 10 having two components in the form of strands 12 and 14 (and because *Burmeister* does not indicate otherwise), a reader skilled in the art, would reasonably interpret the *Burmeister* stent to have structural elements (*e.g.*, strands 12 and strands 14) that are each formed entirely of a single component, such that at a given time, each structural element is either in a martensitic state or in an austenitic state, but not in both states.

In contrast to the *Burmeister* stent, Applicant discloses a stent with structural elements that are distinct from the corresponding sensor elements, such that the sensor elements do not form the entire stent structure itself as is the case in the *Burmeister* stent. Instead, the sensor elements of the claimed invention form a portion of the stent structure. Applicant references page 23, lines 22-26 of the originally filed application, which reads:

> Alternatively, portions of the wall elements 32, 36 may be fabricated of a first material having a transition point T_1, while other portions of the wall elements 32,

> 36, which are preferably non-structural for the sensor device 30 under the T_1 conditions, but are structural for the sensor device 30 under T_2 conditions, are fabricated of a second material having a transition point T_2. [Emphasis added]

During examination of the pending application, the Examiner repeatedly argues that *Burmeister* purportedly discloses "laminated" structural elements.[1] To support this argument, the Examiner references *Burmeister*, column 6, lines 27-36. The referenced passage reads:

> Stent 30 is comprised of at least two layers 32 and 34, one of which 32 is a Ni-Ti alloy (50.8 atomic wt. % Ni, balance Ti, transition temperature of A_f=0° C) and normally in the austenitic state, the other of which 34 is a Ni-Ti (49.4 atomic wt. % Ni, balance Ti, transition temperature A_f = 60° C) and normally in the martensitic state. Preferably, the inner layer is 32 and the outer layer is 34. However, this may be reversed and also a plurality of layers, alternating or otherwise, may be utilized in this particular embodiment.

Applicant notes that the terms "laminated" and "structural elements" do not exist anywhere in *Burmeister*. Having the same terminology in the prior art as in the patent application is not necessary in order to find anticipation. Nonetheless, to establish a *prima facie* case of anticipation, the Examiner is still obligated to clearly identify expressions of equivalent meaning and provide clear explanations with regard to his opinion as to which element in the prior art reference corresponds to an equivalent element in the examined application. By not clearly defining which specific elements in the prior art purportedly correspond to "first structural elements", "first sensor element", "second structural elements", and "second sensor element",

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[1] *See* third paragraph on page 2 of the Final Office Action of May 15, 2006, wherein the Examiner declares:

> Burmeister discloses stent conformations that comprise at least two structural elements that can be laminated, e.g. the stent of figure 1, which comprises strands 12 and 14, each of which may comprise an austenitic layer which can act as a "sensor" as claimed... The structural element of strands 12 could be considered the martensitic layer, which is capable of expanding, e.g. by balloon as disclosed in Burmeister, and the self-expanding austenitic layer of strand 12 could be considered the sensor element. Strands 14 would have similar layers. [Emphasis added]

See also third paragraph on page 2 of the Non-Final Office Action of October 5, 2005, wherein the Examiner declares:

> The structural elements of Burmeiter [sic] et al. also comprise a laminate structure with layers having different martensite transition temperatures and therefore some of its plurality of structural elements further comprise at least one sensor. [Emphasis added]

See also second paragraph on page 4 of the Final Office action of December 23, 2004, wherein the Examiner declares:

> Burmeiter [sic] et al. discloses an implantable sensor device made of a superelastic material (col. 4, lines 31-57) which can be laminated (col. 6, lines 27-36) having a plurality of structural elements capable of expanding within an anatomical passageway... [Emphasis added]

Applicant submits that the Examiner has failed to adequately establish a *prima facie* case of anticipation. *See In re Sun*, 22 F.3d 1102 (Table) (Fed. Cir. 1993) (confirming that the examiner bears the burden of presenting a *prima facie* case of anticipation).

While *Burmeister* does disclose an embodiment (as illustrated in Figure 3) that may be considered to have two layers laminated to each other, the embodiment referenced by the Examiner (as illustrated in Figure 1) to form the basis for his anticipation rejection does not have laminated layers. Instead, in the embodiment illustrated in Figure 1 of *Burmeister*, two metal strands are braided and woven around each, thereby forming a braided, interwoven stent. To characterize this specific arrangement as illustrated in Figure 1 as being "laminated", as the Examiner has done, is a mischaracterization of the prior art.[2] Moreover, contrary to the Examiner's assertion that strand 12 in *Burmeister* Figure 1 possesses two layers, one in a martensitic phase and one in an austenitic phase, there is absolutely no mention of this characteristic anywhere in *Burmeister*.

The only embodiment in *Burmeister* that possesses a multi-layer embodiment, as suggested by the Examiner, is the embodiment illustrated in Figure 3. However, this embodiment fails to anticipate the invention of claims 48-49 and 51-66 because the described individual layers 32, 34, if interpreted to be first and second structural elements, would not have distinct first and second sensor elements for the simple fact that each described layer 32, 34 is formed of a single component. Now, if the Examiner interprets the combination of layer 32 and layer 34 to collectively form a first structural element, the embodiment of *Burmeister* Figure 3 still fails as an anticipatory reference because it does not disclose a second structural element, as recited in claim 48.

Applicant acknowledges that, hypothetically, the Examiner's rejection may have been appropriate had claim 48 omitted references to sensor elements and instead read as follows:

> 48. An implantable ~~sensor~~ device having a plurality of structural elements capable of expanding within an anatomical passageway comprising first and second structural elements ~~where at least some of the plurality of first structural elements further comprise at least one first sensor element and where at least some of the plurality of second structural elements further comprise at least one second sensor element, both sensors~~ which selectively detect an energy stimulus and responds to the detection of the energy stimulus by altering the geometry or conformational profile of the device body member.

[2] *See* Merriam's Online Dictionary at <http://www.m-w.com/cgi-bin/dictionary>, which defines the term "laminated" as meaning "composed of layers of firmly united material."

However, unlike the above hypothetical claim, pending claim 48 actually does make specific references to sensor elements, more specifically, sensor elements which do not form the entire stent themselves. Thus, the claimed sensor elements are to be construed as being distinct from the structural elements. Accordingly, because *Burmeister* does not teach a stent with sensor elements that form distinct elements from structural elements, *Burmeister* fails as an anticipatory reference.

B. The strands described in the two-component *Burmeister* stent do not qualify as a sensor.

Even assuming *arguendo* that somehow the Board does not interpret the claimed invention's structural elements as being distinct from the recited sensor elements, the Examiner's anticipation rejection still fails because the *Burmeister* stent does not qualify as a sensor. In fact, nowhere in *Burmeister* is there a reference to the term "sensor" or a word with an equivalent meaning.

Under the Examiner's unconventional interpretation of the term "sensor" (*i.e.*, anything that is "inherently detectable" qualifies as a sensor), almost any object under the sun would qualify as a sensor. *See* Final Office Action of May 18, 2006, at page 3. Based on the Examiner's unconventional interpretation, even a human person could theoretically qualify as a "pressure sensor" because a human person would "inherently detect" and respond to a punch (pressure stimulus) to his stomach by wincing in pain (response), in a manner that would be visible and detectable to a casual observer. Similarly, under the Examiner's unconventional definition of a sensor, even a light bulb would qualify as a "position sensor" because a light bulb's condition (*i.e.*, lit or unlit) is dependent on the position of an on/off switch, all of which is "inherently detectable" by, and visible to, a casual observer. In other words, a lit light bulb would indicate that the switch is in an on position, while conversely, an unlit light bulb would indicate that the switch is in an off position.

Needless to say, those skilled in the art would not construe a light bulb or a human being to be a sensor. Likewise, those skilled in the art would not interpret the *Burmeister* stent as having sensors. Contrary to the Examiner's suggestion, mere possession of "radiopaque portions or coatings" would not automatically render an object (*e.g.*, stent) to be a sensor. In contrast to the Examiner's unconventional definition of the term "sensor" (*i.e.*, anything that is "inherently

detectable"), Webster's Online Dictionary <http://www.m-w.com> defines a sensor as "a device that responds to a physical stimulus (such as heat, light, sound, pressure, magnetism, or a particular motion) and transmits a resulting impulse (as for measurement or operating a control)." [Emphasis added] As understood by those skilled in the art, "radiopaque portions or coatings" do not constitute a device, nor do they transmit a resulting impulse. Thus, the "radiopaque portions or coatings" described in *Burmeister* do not constitute a sensor, as commonly understood by those skilled in the art, nor would their mere presence on an object render the object to be a sensor. Despite Applicant's specific request (as noted in pages 5-6 of Applicant's Response to the Final Office Action of May 18, 2006), the Examiner has failed to cite a reference that specifically: (1) classifies a radiopaque coating as a sensor; or (2) teaches that the mere presence of a radiopaque coating on an object automatically renders said object to be a sensor because said object would be "inherently detectable with non-invasive radiographs, especially when using radiopaque portions or coatings" (*i.e.*, the Examiner's unsupported standard for qualifying an object as a sensor).

With reference to paragraph 6 of *Burmeister*, Applicant notes that the *Burmeister* stent is designed for use "in a multiple component arrangement which allows for initial self-expansion and subsequent deformation to a final enlarged diameter in the body." [Emphasis added] Furthermore, the purpose of this specific design is to "control the degree of expansion [of the stent] and hence the degree of embedment in the vessel wall." [Emphasis added] *See Burmeister*, paragraph 8. In other words, after implantation, the *Burmeister* stent is designed to enter into a passive state, whereby the stent's physical properties theoretically remain constant and are not intended to react/respond to internal conditions of the body, let alone react/respond to an externally applied energy/stimulus, as recited in pending claim 48. Thus, after implantation and initial expansion, the *Burmeister* stent is not designed to undergo any additional conformational changes within the device. Accordingly, the *Burmeister* stent can not function, and is not even intended to function, as a sensor in the manner suggested by the Examiner, *i.e.*, by stimulating the stent with energy to induce conformational changes.

Indeed, based on the *Burmeister* disclosure, one can reasonably surmise that if the *Burmeister* stent is applied in the manner suggested by the Examiner, *i.e.*, by stimulating the stent with energy to induce conformational changes, all types of technical and safety issues (*e.g.*, stent underexpansion, stent overexpansion, and nonuniform distribution of stent structure) would

arise, thereby leading to various potentially life-threatening complications. For instance, if inducement of conformational changes of the *Burmeister* stent, as suggested by the Examiner, leads to stent underexpansion, post-stent restenosis and blood vessel occlusion would likely occur, thereby potentially leading to chest pains and perhaps even heart attacks. Conversely, if inducement of conformational changes of the *Burmeister* stent, as suggested by the Examiner, leads to stent overexpansion, the patient may suffer increased trauma and inflammation. In fact, stent overexpansion may even lead to tearing and rupture of the blood vessel, leading to aneurysm and possible death.

Clearly, the Examiner's suggestion of inducing conformational changes in the *Burmeister* stent is diametrically opposed to *Burmeister's* purpose of "control[ling] the degree of expansion [of the stent] and hence the degree of embedment in the vessel wall." *See Burmeister*, paragraph 8. Indeed, the Examiner's proposed use of the *Burmeister* stent would render it inoperable and ineffective as a working stent.

In contrast to the *Burmeister* stent, Applicant's stent is distinctively designed with sensor elements that have the specific purpose of undergoing conformational changes. Thus, Applicant's invention, in fact, does incorporate a sensor element (one that is recognized by those skilled in the art to be a sensor) onto the stent structure. After implantation into the body, the claimed stent eventually reaches an equilibrium condition, just like the *Burmeister* stent would. However, unlike the *Burmeister* stent, the claimed stent after reaching the equilibrium condition, will not remain in a passive state. Rather, the claimed stent's sensors are specifically designed to detect changes in the energy state proximate the stent and respond to the internal equilibrium environment (*e.g.*, blood pressure, blood temperature, plaque growth or state of endothelialization). What is more, the claimed stent's sensors will also respond to externally applied energy. The externally applied energy/stimulus may be an exogenous energy stimulus such as externally applied temperatures, pressure, microwave, ultrasound, RF, ultraviolet, infrared, magnetic resonance, x-rays, beta, or gamma irradiation. In essence, the claimed stent's sensors selectively detect changes in energy states after being implanted in the *in vivo* environment and will respond to energy state changes. All of this is possible because, in the claimed stent, only portions of the stent structure is formed of sensor elements, whereas in *Burmeister*, the components (interpreted by the Examiner to be sensor elements) form the entire stent structure.

To conclude, Applicant submits that *Burmeister* fails to teach, expressly or implicitly, the capability to detect/respond to internal energy proximate the stent and the capability to detect/respond to externally applied energy. Moreover, as discussed above, the *Burmeister* stent is not effectively capable of undergoing, and is not intended to undergo, conformational changes after implantation. Thus, it would be clearly understood by those skilled in the art that *Burmeister* does not teach a sensor stent, nor does *Burmeister* teach incorporating sensors onto a stent. For the foregoing reasons, Applicant submits that the anticipation rejection of the claims under 35 U.S.C. §102(b) and based on *Burmeister* is legally insufficient.

C. *Burmeister* does not Enable the Claimed Invention

Even assuming *arguendo* that *Burmeister's* "radiopaque portions or coatings" somehow do constitute sensors -- a position Applicant strongly opposes -- the Examiner's anticipation rejection would still be improper because *Burmeister* would not qualify as an enabling prior art reference with regard to Applicant's pending claims. Courts have consistently held that for a prior art reference to anticipate a claimed invention, the prior art reference must be enabling. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 200) (stating that "a claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled ... a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if the disclosure fails to 'enable one of skill in the art to reduce the disclosed invention to practice' " and quoting from *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1962)).

Moreover, according to the Federal Circuit, "[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate ... The disclosure in the assertedly anticipating reference must be adequate to enable possession of the desire subject matter. It is insufficient to name or describe the described subject matter, if it cannot be produced without undue experimentation." [Emphasis added] *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 346 F.3d 1051, 1054-1055 (Fed. Cir. 2003). In short, in order "[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." [Emphasis added] *PPG Indus. V. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996); *see also Minnesota Mining and*

Manufacturing Co. v. Chemque, Inc., 303 F.3d 1294, 1301 (stating that enablement requires that "the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation"); *see also In re Borst*, 345 F.2d 851, 855 (CCPA 1962) (holding that "the disclosure must be such as will give possession of the invention to the person of ordinary skill. Even the act of publication or the fiction of constructive reduction to practice will not suffice if the disclosure does not meet this standard.")

In regard to the Examiner's anticipation rejection, Applicant submits that *Burmeister* does not provide any disclosure, let alone sufficient disclosure, to enable those skilled in the art to practice the implantable stent device invention recited in pending claims 48-49 and 51-66. More specifically, *Burmeister* does not provide any disclosure for constructing the claimed stent, which is specifically designed for responding to, and for selectively detecting, an energy stimulus. In fact, *Burmeister* provides utterly no detail as to whether its stent would even respond to an energy stimulus, let alone how it would respond to the energy stimulus and how it would be constructed in a manner that would allow it to selectively detect the stimulus and respond to it.

As described in greater detail in Section B above, the *Burmeister* stent is specifically designed to enter into a passive state after implantation, wherein the stent's physical properties are designed to remain constant and are not intended to react and respond to a stimulus. Thus, *Burmeister's* teachings actually enable the construction of a stent that remains in a constant passive state after implantation. More correctly, *Burmeister's* teachings actually enable the construction of a stent that optimally does not respond to a stimulus. In fact, responding to a stimulus and undergoing geometrical or conformational changes is an undesirable result in regard to operation of the *Burmeister* stent. Simply put, *Burmeister's* teachings actually go against Applicant's teaching of a stent designed to respond to and detect a stimulus. Thus, *Burmeister* provides disclosure that enables the construction of a stent that, operationally, is diametrically opposed to the claimed invention.

Following up on Section B, Applicant again notes that *Burmeister* makes no mention of the term "sensor" or any other term with an equivalent meaning. By not describing how its stent would operatively function as a sensor, *Burmeister* cannot serve as an enabling disclosure with respect to anticipating a stent having sensor elements, as recited in the pending claims.

Conclusion

An anticipation rejection under 35 U.S.C. §102(b) requires that there be identity between the claimed elements and the cited prior art references. Such identity is unequivocally absent between the elements of the rejected claims and the *Burmeister* reference. In the absence of such identity, Applicant respectfully solicits the Board to reverse the Examiner's rejections and allow claims 48-49 and 51-66.

Respectfully submitted,

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8. Claims Appendix

The following is a listing of the claims on appeal.

Claims 1-47. Cancelled.

Claim 48. An implantable sensor device having a plurality of structural elements capable of expanding within an anatomical passageway comprising first and second structural elements where at least some of the plurality of first structural elements further comprise at least one first sensor element and where at least some of the plurality of second structural elements further comprise at least one second sensor element, both sensors which selectively detect an energy stimulus and responds to the detection of the energy stimulus by altering the geometry or conformational profile of the device body member.

Claim 49. The implantable sensor device according to Claim 48, wherein the structural elements are fabricated of a forming material selected from the group consisting of shape memory materials, superelastic materials, plastically deformable materials, and elastically deformable materials.

Claim 50. Cancelled.

Claim 51. The implantable sensor device according to Claim 49, wherein the energy stimulus comprises an exogenous energy stimulus selected from the group consisting of microwave, ultrasound, radio frequency, ultraviolet, infrared, magnetic resonance, x-rays, laser, and beta and gamma irradiation.

Claim 52. The implantable sensor device according to Claim 51, wherein the exogenous energy stimulus results in localized heating in vivo.

Claim 53. The implantable sensor device according to Claim 52, wherein the exogenous energy stimulus is a laser delivered by a laser catheter.

Claim 54. The implantable sensor device according to claim 49, wherein the energy stimulus is a physiological stimulus.

Claim 55. The implantable sensor device according to Claim 54, wherein the physiological stimulus comprises an endogenous energy stimulus selected from the group consisting of fluid pressure, fluid shear forces, body temperature, cellular binding and molecular binding.

Claim 56. The implantable sensor device according to Claim 49, further comprising a sensor element that facilitates the interaction with the energy stimulus and mediates the altering of the geometry or conformational profile of the device body member.

Claim 57. The implantable sensor device according to Claim 56, wherein the sensor element comprises a plurality of sensor regions integrally defined on at least one of a luminal or abluminal surface of the device body member.

Claim 58. The implantable sensor device according to Claim 57, wherein the sensor regions are fabricated of a shape memory or superelastic material so that the properties of the sensor regions differ from that of the remaining structural elements.

Claim 59. The implantable sensor device according to Claim 58, wherein the sensor regions exhibit a martensitic transition temperature higher than that of the remaining structural elements.

Claim 60. The implantable sensor device according to Claim 59, wherein upon the sensor regions undergoing martensitic transformation, the sensor region stimulates the remaining structural elements to undergo martensitic transformation and effect a change in the geometry of the implantable sensor device.

Claim 61. The implantable sensor device according to Claim 60, wherein the implantable sensor device displays an altered geometry that produces an image detectable using non-invasive imaging techniques.

Claim 62. The implantable sensor device according to Claim 48, wherein the altered geometry or altered conformation is capable of detection by non-invasive imaging techniques.

Claim 63. The implantable sensor device according to Claim 62, wherein the implantable sensor device further comprises structural elements having areas of inclusion of superelastic material, wherein the superelastic material is responsive to externally applied forces resulting in a martensitic transformation in the structural elements having areas of inclusion of superelastic material.

Claim 64. The implantable sensor device according to Claim 63, wherein the externally applied forces is a force selected from the group consisting of ultrasound, irradiation, microwave, radio frequency, ultraviolet, infrared, magnetic resonance, x-rays and gamma irradiation.

Claim 65. The implantable sensor device according to Claim 48, wherein the structural elements form the walls of the sensor device, the structural elements being fabricated of laminate layers of shape memory or superelastic material.

Claim 66. The implantable sensor device according to Claim 65, wherein the structural elements are formed of at least two laminate layers, wherein a first laminate layer has a first martensitic transition point at normal physiological temperature and a second laminate layer has a second martensitic transition point that is greater than the first martensitic transition point.

Claim 67. Cancelled.

9. Evidence Appendix

None.

10. Related Proceedings Appendix

None.